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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

NATALIYA BORCHENKO, On Behalf of Herself and All Others Similarly Situated,

Plaintiff,

v.

L'ORÉAL USA, INC., a Delaware corporation,

Defendant.

Case No.: **2:19-cv-01427-R-AS**
2:19-cv-01426-R-AS

PLAINTIFF'S OPPOSITION TO DEFENDANT L'OREAL USA, INC.'S MOTION TO DISMISS OR, IN THE ALTERNATIVE, TO STAY UNDER PRIMARY JURISDICTION

Date: June 17, 2019
Time: 10:00 a.m.
Crtrm: 880

The Hon. Manuel Real
Trial Date: TBD

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Plaintiff's Class Action Complaints (Dkt. No. 1 ("Compl."))[1] each assert a single claim against Defendant – an unlawful business act or practice in violation of § 17200 of the UCL. By representing that its Revitalift® and Garnier skin care products (the "Products") affect the structure of consumers' skin by repairing and/or reducing wrinkles; lifting the skin; and firming and tightening (Garnier products) or firming and redensifying (Revitalift® products) the skin[2] (collectively the "skin structural representations"); the Products are cosmetic drugs as defined under California's Sherman Law, which adopts all FDCA nonprescription drug regulations. Compl. ¶¶ 25-26 (citing Cal. Health & Safety Code §109925(a)[3]). Defendant arguably agrees, as it inserted the word "appearance" immediately before its description of the label claims in its opening paragraph (Motion at 1), in an effort to undercut their structural significance even though the claims are not qualified by the word "appearance" on the Product labels. Compl. ¶ 7. Accordingly, the Products are being unlawfully sold because Defendant has not obtained the required FDA pre-market approval through the New Drug Application ("NDA") process. *Id.* at ¶¶ 8-10, 22-34.

Defendant seeks dismissal on three grounds, all lacking merit: (1) no UCL standing; (2) preemption; and (3) primary jurisdiction.

First, the Ninth Circuit recently held that a plaintiff has both Article III and UCL standing where she alleges that a product is a "drug", is sold without FDA

[1] Because Defendant's Memorandum (Dkt. No. 22-1 (L'Oreal Revitalift, Case No. 2:19-cv-01427-R-AS) and Dkt. No. 15-1 (Garnier, Case No. 2:19-cv-01426-R-AS) (collectively, "Motion") addresses both cases, citations to "Compl." herein refer to the complaints in both actions. Citations to the L'Oreal Revitalift complaint, specifically, will be indicated by "Revitalift Compl.", and citations to the Garnier complaint will be indicated by "Garnier Compl."

[2] Defendant also represents that certain of the Revitalift products will "repair the skin barrier" and "strengthen[], and repair[] skin barrier" (Revitalift Compl. ¶ 5) and that certain of the Garnier products will "restore" or "improve" skin elasticity (Garnier Compl. ¶ 5).

[3] Plaintiff mistakenly cites to § 109925(c). Plaintiff intended to cite to § 109925(a).

approval in violation of the FDCA and Sherman Law, and, as a result, plaintiff spent money on a product that should not have been on the market. *Franz v. Beiersdorf, Inc.*, 2018 WL 6519527 (9th Cir. Dec. 11, 2018) ("*Franz* 9th Cir.").[4] That is precisely what Plaintiff alleges here. Compl. ¶¶ 2-6, 9-10, 15, 22-26, 48. Defendant attempts to undercut the significant guidance that the *Franz* 9th Cir. opinion provides by placing it in a footnote (Motion at 23-24, fn. 16), and making the conclusory argument that the Ninth Circuit "got it wrong" – neither of which is persuasive, let alone a basis for this Court to rule differently.

Second, the California Supreme Court has held that UCL unlawful claims, like Plaintiff's, that do not seek "to enforce the FDCA" but are instead based on violations of California's Sherman Law, are not preempted. *Farm Raised Salmon Cases*, 175 P.3d 1170 (Cal. 2008). Such actions are not precluded even if the FDA might not pursue the action under the FDCA. *Id.* at 1184.

Finally, several courts have determined in the first instance whether a product's objective intended use indicates that the product is a cosmetic "drug." *See, e.g., F.T.C. v. Pantron I Corp.*, 33 F.3d 1088, 1104-05 (9th Cir. 1994) ("*Pantron I*") (affirming district court's finding that defendant's hair product is a "drug"); *U.S. v. Article Consisting of 36 Boxes, More or Less, Labeled "Line Away Temporary Wrinkle Smoother, Coty"*, 415 F.2d 369, 372 (3d Cir. 1969) ("*Line Away*") (same regarding lotion product); *U.S. v. An Article ... Consisting of 216 Indiv. Cartoned Bottles, More or Less, of an Article Labeled in part: Sudden Change*, 409 F.2d 734, 738-42 (2d Cir. 1969) ("*Sudden Change*") (finding lotion product making skin lifting representations was a drug); *Allergan Inc. v. Athena Cosmetics*, 738 F.3d 1350, 1356 (Fed. Cir. 2013) ("*Allergan II*") (affirming district court's order that objective intended use of RevitaLash products indicated they

[4] Although unpublished, Plaintiff may properly cite the *Franz* 9th Cir. opinion pursuant to Ninth Circuit Rule 36-39(b) and F.R.A.P. 32.1.

were drugs). As the FDA has provided clear guidance on this issue, this Court is fully capable of resolving Plaintiff's UCL unlawful claim. Further, the FDA recently declined to take action on a similar cosmetic drug claim referred to it by this district court. *Franz v. Beiersdorf, Inc.*, No. 14-cv-02241-LAB-RBB, Dkt. No. 37-1, FDA's response to plaintiff's Citizen Petition (Ex. A to the Declaration of Patricia N. Syverson ("Syverson Decl."), filed herewith).

As fully set forth below, Defendant's Motion should be denied in its entirety.

I. ARGUMENT

A. Legal Standard

As Defendant asserts the Complaints are insufficient on their face to invoke federal jurisdiction, "[P]laintiff is entitled to safeguards similar to those applicable when a Rule 12(b)(6) motion is made." *Lopez v. Stages of Beauty, LLC*, 307 F. Supp. 3d 1058, 1065 (S.D. Cal. 2018) (internal quotations omitted). The Court must "limit[] its inquiry to the allegations set forth in the complaint" (*id.*) and accept them as true. *Alvarez v. U.S.*, 2017 WL 3723926, at *1 (S.D. Cal. Jan. 17, 2017).

B. Plaintiff Has Standing as Reliance is Not Required and She Spent Money on Products that Should Not Have Been on the Market

Plaintiff has Article III standing as she suffered an "injury in fact" that has a "causal connection" with the conduct complained of that is "likely" to be "redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). And, contrary to Defendant's argument, she also has UCL standing as she "suffered injury in fact" and "lost money or property as a result of the unfair competition." Cal. Bus. & Prof. Code § 17204.

Both standing issues were recently resolved by the Ninth Circuit in favor of standing in the materially identical *Franz* case:

> Plaintiff has standing under California's Unfair Competition Law

> ("UCL"). ***Plaintiff alleges that Defendant sold a "drug" – Nivea CoQ10 – without FDA approval. Plaintiff contends that doing so violates the Food, Drug, and Cosmetic Act ("FDCA"), see 21 U.S.C. §§ 331(d), 355(a), and California's Sherman Law, see Cal. Health & Safety Code § 111550. Plaintiff alleges that, as a result she spent money on a product that should not have been on the market. Those allegations are sufficient to establish standing under the UCL.*** *See Medrazo v. Honda of N. Hollywood*, 205 Cal. App. 4th 1, 11-13 (2012), modified on denial of reh'g (Apr. 16, 2012).
>
> …
>
> Plaintiff likewise has standing under Article III of the United States Constitution. ***Plaintiff alleged injury in fact – she spent money on Nivea CoQ10. Defendant's allegedly illegal conduct caused that injury, insofar as Defendant allegedly sold a product in commerce that it should not have sold.*** And the injury is redressable – in restitution – by a favorable court decision. *Spokeo, Inc. v. Robbins*, 136 S. Ct. 1540, 1547 (2016). ***The district court erred by dismissing Plaintiff's claim on the ground that she lacked standing.***

Franz 9th Cir., 2018 WL 6519527, at *1-2 (emphases added).

Plaintiff likewise alleges: (1) the Products claim to affect the structure of consumers' skin, making it a "drug" (Compl. ¶ 6); (2) Defendant did not obtain the required pre-market FDA approval through the NDA process such that Defendant has been selling the Products unlawfully (*id.* at ¶¶ 8-10); and (3) "but for Defendant's illegal conduct," the Products would not have been on the market" and Plaintiff would not have spent money on the Products. *Id.* at ¶ 48. *See also In re Hydroxycut Mktg. & Sales Practices Litig.*, 801 F. Supp. 2d 993, 1002 (S.D. Cal.

2011) ("Monetary harm is a classic form of injury-in-fact" (internal quotations omitted)); *Brazil v. Dole Food Co.*, 935 F. Supp. 2d 947, 961 (N.D. Cal. 2013) (allegation that plaintiff spent money that he would not have absent defendants' claims constitutes "a quintessential injury-in-fact"); *Lanovaz v. Twinings N. Am., Inc.*, 2013 WL 675929, at *6 (N.D. Cal. Feb. 25, 2013) (holding that "[t]he alleged purchase of a product that plaintiff would not otherwise have purchased but for the alleged unlawful label is sufficient to establish an economic injury-in-fact"); *Ivie v. Kraft Foods Global, Inc.*, 2013 WL 685372, at *4 (N.D. Cal. Feb. 25, 2013) (same).

The Ninth Circuit also made clear that Plaintiff need not plead reliance as she alleges an "unlawful" claim not based on fraud. As such, Defendant's argument that Plaintiff's theory of standing is "conjectural" because she does not allege that she relied upon the Product's status as a "drug" (Motion at 24-25), fails:

> ***Plaintiff need not plead reliance because neither the alleged FDCA violation nor the alleged Sherman Law violation requires allegations of fraud or deception.*** *See id.* at 12 (explaining that claims based on a theory of fraud require a plaintiff to demonstrate reliance to establish standing because "reliance is the causal mechanism of fraud." (quoting *In re Tobacco II Cases*, 46 Cal. 4th 298, 326 (2009))).

Franz 9th Cir., 2018 WL 6519527, at *1 (emphasis added).[5] A sensible result given that consumers have no way of knowing whether the Products are "drugs" or whether they are being sold unlawfully. Instead, consumers reasonably assume that products they buy in retail stores are being sold lawfully. It is incumbent on

[5] Because Plaintiff bases her UCL claim solely on the unlawful sale of the Products and does not challenge whether the skin structural representations are true, as Defendant repeatedly recognizes (*E.g.*, Motion at 1, 2, 21-22), it is irrelevant whether the Products would obtain FDA approval had Defendant sought it. *Id.* at 24. And, although unnecessary, Plaintiff also alleges she read the skin structural representations and purchased the Products because of them and would not have done so but for the skin structural representations. Compl. ¶¶ 15, 48.

Defendant, as the Products' manufacturer who is charged with knowledge of the law governing its sale of the Products, to ensure that the Products comply with all applicable laws. That is why the UCL focuses on the conduct of the defendant. *See, e.g.*, *In re Tobacco II Cases*, 207 P.3d 20, (Cal. 2009) ("The substantive right extended to the public by the UCL is the right to protection from fraud, deceit and unlawful conduct, and the focus of the statute is on the defendant's conduct.") (internal quotations and citations omitted).

The cases Defendant cites are factually distinguishable. As the Ninth Circuit explained, *Demeter v. TAXI Comput. Servs., Inc.*, 21 Cal. App. 5th 903 (2018) and *Medina v. Safe-Guard Prods., Int'l, Inc.*, 164 Cal. App. 4th 105 (2008) (Motion at 22-23), are not on point because they "concerned voidable service contracts", whereas this case "concern[s] goods that a defendant was allegedly not legally allowed to sell in the form being offered". *Franz* 9th Cir., 2018 WL 6519527, at *1. The same is true of *Peterson v. Cellco P'ship*, 164 Cal. App. 4th 1583, 1590 (2008) (UCL claim predicated on sale of cell phone insurance without a license) (Motion at 22-23). In none of these cases, unlike here, did plaintiffs allege they lost any money as a result of defendants' conduct.

In *Davis v. RiverSource Life Ins. Co.*, 240 F. Supp. 3d 1011 (N.D. Cal. 2017) (Motion at 24-25), the court granted leave to amend a UCL claim based on insurance code violations, where plaintiff failed to "allege that the charge would not have been imposed, or would have been less, had Defendants complied with the Insurance Code" or that "he would not have purchased the policies…but for Defendants' alleged statutory noncompliance." Plaintiff alleges both here. Compl. ¶¶ 11, 15, 33-34, 48. And, in *Klein v. Avis Rent a Car Sys. Inc.*, 2009 WL 151521 (C.D. Cal. Jan. 21, 2009) (Motion at 25), the court similarly granted leave to amend a UCL claim based on an insurance code violation, where plaintiff "did not assert that he personally paid an excessive rate for insurance" and did not allege which

insurance product he purchased, as a result of defendants' unlawful conduct. Plaintiff's Complaint does not suffer from these pleading omissions. *See* Compl. ¶¶ 15, 33, 48.

And, in *Animal Legal Def. Fund v. Mendes*, 160 Cal. App. 4th 136 (2008) (Motion at 22, fn. 15), involving claims that milk producers allegedly violated a law requiring that cows have adequate exercise area, plaintiffs failed to allege that the defendant milk producers sold or produced the milk the consumers purchased and, thus, the court found that plaintiffs received the benefit of their bargain and suffered no economic injury. Here, Plaintiff purchased Defendant's unlawful Products.

Thus, Plaintiff has properly alleged both Article III and UCL standing.

C. Plaintiff's UCL Unlawful Claim is Not Preempted Because It is Based Upon the Sherman Law, Which Parallels the FDCA

There is a strong presumption against preemption. *Farm Raised Salmon Cases*, 175 P.3d at 1076. That presumption applies "with particular force" here, because "[c]onsumer protection laws such as the UCL … are within the states' historic police powers." *Id.* (internal quotations omitted). Defendant bears the burden of overcoming this presumption and demonstrating that Plaintiff's claim is preempted. *Id.* Defendant does not meet its steep burden.

Defendant's primary preemption argument is that Plaintiff seeks to "privately enforce" the FDCA and "require L'Oréal either to comply with an FDA monograph or submit an NDA", and Plaintiff is prohibited from doing so by 21 U.S.C. § 337. Motion at 3, 7-12. No. As Defendant recognizes, it could "withdraw[] the claims from the labeling" (Motion at 4) in lieu of filing an NDA. And, as in *Farm Raised Salmon Cases*, Plaintiff seeks to enforce the UCL, which makes it unlawful to violate the Sherman Law. FAC ¶¶ 32-41. There, plaintiffs brought a UCL unlawful claim based on defendants' sale of artificially colored farmed salmon without disclosing the use of artificial coloring, in violation of the FDCA and

Sherman Law. 175 P.3d at 1173-74. Defendants demurred to plaintiffs' complaint, arguing – like Defendant argues here – that section 337(a) preempts plaintiffs' state law claims. *Id.* The trial court sustained the demurrer, and the Court of Appeal affirmed. *Id.* at 1074. The California Supreme Court reversed, finding that "Defendants' starting assumption is incorrect. Plaintiffs do not seek to enforce the FDCA; rather, their [claims] are predicated on violations of obligations imposed by the Sherman Law, something that state law undisputedly allows." *Id.* at 1181.

The California Supreme Court also squarely rejected Defendant's argument that it makes no difference that Borchenko also refers in her claim to California's Sherman Law because the Sherman Law merely adopts the FDCA as California law (Motion at 9), stating:

> That the Sherman Law imposes obligations identical to those imposed by the FDCA, as it must under section 343–1, does not substantively transform plaintiffs' action into one seeking to enforce federal law. Rather, it merely reflects Congress's considered judgment that states should uniformly regulate food labeling using identical standards.

175 P.3d at 1181.

Defendant's 2-page treatment of *Farm Raised Salmon Cases* – without much in the way of case law support (Motion at 11-12) – is an implicit acknowledgement of its applicability here, and Defendant's attempts to distinguish it fall short. First, although *Farm Raised Salmon Cases* was decided before *Perez v. Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013), federal courts exercising diversity jurisdiction apply the substantive law of the forum state (*Rumberg v. Weber Aircraft Corp.*, 424 F. Supp. 294, 298 (C.D. Cal. 1976) (citing *Erie R. Co. v. Tompkins*, 304 U.S. 64, 58 (1938)) – and *Farm Raised Salmon Cases* is an opinion by the highest court in the forum state. Second, because Plaintiff is suing to enforce the UCL, which is within the

states' "historic police powers", there is certainly a "presumption against preemption" which applies "with particular force." *Farm Raised Salmon Cases*, 175 P.3d at 1076. Third, *Pediamed Pharmaceuticals v. Breckenridge Pharm.*, 419 F. Supp. 2d 715, 726-27 (D. Md. 2006), did not include a state law claim that parallels the FDCA – the defendants' unclean hands argument "require[d] direct application of the FDCA". Here, Plaintiff's UCL claim, like the claim in *Farm Raise Salmon Cases*, alleges a violation of a state-law duty that is parallel to, but *independent of*, the requirements of the FDCA.

Since *Farm Raised Salmon Cases*, district courts routinely reject arguments that state law UCL claims and related claims under the Sherman Law are impliedly preempted under section 337(a) and *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). This district court (Judge Wright) recently confirmed that UCL claims predicated on violations of the Sherman Law are not preempted. In *In re Trader Joe's Tuna Litig.*, 289 F. Supp. 3d 1074, 1081 (C.D. Cal. 2017), plaintiffs' SAC asserted claims under the Sherman Law, unlike prior complaints that only alleged violations of the "federally mandated minimum standard of fill". In determining that plaintiffs' claims were not preempted, the court explained:

> [w]e must ask whether Plaintiffs would have a claim if the Sherman Law specifically set forth the Pressed Weight Standard, instead of incorporating the FDCA requirements by reference. If Plaintiffs would have a claim based on state-law in that scenario, then Plaintiffs' claims are predicated on an independent state-law violation that parallels a federal duty. In that instance, Plaintiffs would not be relying on the FDCA, but rather the standard set forth in California's Sherman Law. The fact that the California law does not specifically set forth the Pressed Weight Standard results from consideration of practicalities. If

> California were required to update its statutes every time the federal government changed a standard, it would constantly have statutes stating standards that did not mirror the federal scheme, which would then be expressly preempted by Section 343-1(a).

Id. at 1084.[6] The same reasoning applies here.

Other courts agree. *See, e.g.*, *Patane v. Nestle Waters N. Am., Inc.*, 2019 WL 1398052, at *4 (D. Conn. Mar. 28, 2019) (plaintiffs' claims not preempted where a state "outright adopt[s] an FDCA standard and then [] a plaintiff [sues] under state law for the violation of that standard" rather than suing "under a generic state law claim (such as for fraud, breach of contract, or unfair trade practices) that would not be actionable absent a violation of the FDCA standard", because plaintiffs' claims are "based on an independent state law duty, even if the State has chosen merely to incorporate or otherwise track a federal law standard); *Vassigh v. Bai Brands LLC*, 2015 WL 4238886, at *4-5 (N.D. Cal. July 13, 2015) (courts "routinely reject" argument that UCL claim based on state laws identical to the FDCA are preempted by the FDCA (collecting cases)); *Hesano v. Iovate Health Sciences, Inc.*, 2014 WL 197719, at *7 (S.D. Cal. Jan. 15, 2014) ("The FDCA therefore does not preclude states from adopting their own parallel laws and adopting a different mechanism for enforcing those laws. California chose to exercise this right by enacting the Sherman Law and allowing private plaintiffs to enforce that law through the UCL.") (citing *Trazo v. Nestle USA, Inc.*, 2013 WL 4083218, at *6 (N.D. Cal. Aug. 9, 2013)).

None of Defendant's cases support preemption here. Unlike here and *Farm*

[6] Judge Wright did not "misinterpret" *Farm Raised Salmon Cases* in *Trader Joe's*, as Defendant argues (Motion at 11, fn. 9). The opinion is clearly reasoned, has not been overturned or otherwise treated negatively, and – as discussed below – other courts have held similarly. And again, California isn't "confer[ring] a private right of action to enforce the FDCA" as Defendant argues. Motion at 11-12, fn. 9. Plaintiff is seeking to enforce the UCL and California's Sherman Law.

Raised Salmon Cases, plaintiffs' claims in *Elkind v. Revlon*, 2015 WL 2344134 (E.D.N.Y. May 14, 2015) (Motion at 8), and *Loreto v. Procter & Gamble Co.*, 515 Fed. Appx. 576, 579 (6th Cir. 2013) (Motion at 7-8), were not based on a state law that parallels the FDCA, such as the Sherman Law. *Elkind*, 2015 WL 2344134, at *9, fn. 4 (plaintiffs' allegations "that the [products] violate the FDCA" do not exist independent of the FDCA and are impliedly preempted); *Loreto*, 515 Fed. Appx. at 579 (same). The same is true of *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1107, 1111-12 (2d Cir. 1997) (Motion at 7) (in action seeking declaration that the defendant lacked standing to bring suit under the Lanham Act and Georgia consumer protection laws arising from its advertising and sale of weight loss products, court affirmed summary judgment for the plaintiff, reasoning that the defendant did not have standing under these laws because his "undeveloped product" was not in competition with the plaintiff's retail products, regardless of whether the plaintiff was selling its products unlawfully in violation of the FDCA).

At issue in *Buckman* was a "state-law fraud-on-the-FDA claim" which the Court found to be impliedly preempted because policing alleged misrepresentations made to federal agencies was not a traditional state function (*see* 531 U.S. at 347-49), unlike Plaintiff's UCL unlawful claim which involves Defendant's unlawful conduct in its sales of the Products *to consumers*, and is within "states' historic police powers." *Farm Raised Salmon Cases*, 175 P.3d at 1076.

Perez v. Nidek Co., 711 F.3d 1109 (9th Cir. 2013), is another fraud-based case, where the court found the laser device off-label omission claims to be expressly and impliedly preempted because, unlike the UCL unlawful claim here which parallels the FDCA, they were "different from, or in addition to" the medical device regulations. *Id.* at 1118. Relevant here is that the court distinguished the case before it from "conduct that *violates* the FDCA" which it recognized is not preempted. *Id.* at 1120 (emphasis original). *Stengel v. Medtronic Inc.*, 704 F.3d

1224 (9th Cir. 2013) (*en banc*) (Motion at 6-7), like this case, falls in the non-preempted latter category as the court upheld plaintiffs' negligent failure to use reasonable care state law claim which paralleled defendant's federal law duty to warn the FDA of adverse health consequences. *Id.* at 1233.

In *Cutler v. Hayes*, 818 F.2d 879 (D.C. Cir. 1987) (Motion at 13), unlike here, plaintiffs challenged the legality of the federal regulations governing review of over-the-counter drugs and the FDA's *duty* to bring enforcement proceedings against all violators of the Act. *Id.* at 885, 893. *Carnohan v. U.S.*, 616 F.2d 1120 (9th Cir. 1980) (Motion at 3) concerned whether the drug Laetrile could be used in a nutritional program for the prevention of cancer.

Tellingly, Defendant's other cases are relegated to footnotes and require no more than short parentheticals to distinguish. Motion at 13-14, fns. 10-11. *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230-31 (3d Cir. 1990) (no Lanham Act false label active vs. inactive ingredient claim where FDA has not determined the ingredients at issue must be labeled as active or inactive); *Arizona v. U.S.*, 567 U.S. 387, 408 (2012) (state unlawful alien law at issue provided greater authority than federal law); *Wisconsin Dept. of Indus. Labor & Human Relations v. Gould Inc.*, 475 U.S. 282, 287 (1986) (state labor law "functions unambiguously as a supplemental sanction" for violation of federal law); *Hoyte v. Am. Nat'l Red Cross*, 439 F. Supp. 2d 38, 44 (D.D.C. 2006) (pursuant to express terms of consent decree government had sole discretion to determine sanctions); *Fraker v. KFC Corp.*, 2007 WL 1296571, at *3 (S.D. Cal. Apr. 30, 2007) (distinguished in *Farm Raised Salmon* cases (175 P.3d at 1183), as alleging "defendant violated the FDCA, misbranded its food in violation of federal regulations, and made actionable health claims in violation of federal regulations"); *Healthpoint Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 840 (W.D. Tex. 2001) (products were admittedly "drugs" and FDA was actively investigating if misbranded).

Thus, Plaintiff concludes where she started with *Farm Raised Salmon Cases*, that allowing Plaintiff to pursue her UCL unlawful claim based on violations of the Sherman Law, which parallels the requirements of the FDCA, does not "expressly conflict with the text of sections 336 and 337" (Motion at 13). *Farm Raised Salmon Cases*, 175 P.3d at 1083 ("We conclude that section 337(a) does not preempt the action as plaintiffs do not seek to 'enforce[], or to restrain violations' of, the FDCA. (§ 337(a).) Rather, plaintiffs' claims … are predicated on state laws establishing independent state disclosure requirements 'identical to' the disclosure requirements imposed by the FDCA, something Congress explicitly approved in section 343–1. (§ 343–1(a)(3).)").

And, although Defendant argues Plaintiff's claims "interfere with FDA's enforcement and regulatory authority" set up by Congress in § 336, such that allowing Plaintiff's claims would "disrupt the enforcement regime that Congress chose" (Motion at 12), as the California Supreme Court recognized, "while allowing private remedies based on violations of state laws identical to the FDCA may arguably result in actions that the FDA itself might not have pursued, Congress appears to have made a conscious choice not to preclude such actions." *Farm Raised Salmon Cases*, 175 P.3d at 1184. Further, even if the FDA would have chosen not to pursue Defendant's violation pursuant to § 336, it is still a violation, nonetheless.

D. The Primary Jurisdiction Doctrine Does Not Apply Because this Court, Like Other Courts Before it, is Fully Capable of Determining Whether the Products are Cosmetic Drugs Given the FDA's Guidance and the Objective Intent-Based Issue Presented

"The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008) (internal quotes omitted); *AICCO, Inc. v. Ins.*

Co. of N. Am., 90 Cal. App. 4th 579, 594 (Cal. Ct. App. 2001). The doctrine of primary jurisdiction "does not require that all claims within an agency's purview be decided by the agency. Nor is it intended to 'secure expert advice' for the courts from regulatory agencies every time a court is presented with an issue conceivably within the agency's ambit." *Brown v. MCI WorldCom Network Servs., Inc.*, 277 F.3d 1166, 1172 (9th Cir. 2002). Rather, primary jurisdiction is to be used only if "a claim 'requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency.'" *Clark*, 523 F. 3d at 1114 (quoting *Brown*, 277 F.3d at 1166)). Plaintiff's claims do not require either and are properly before this Court to determine.

1. Several courts have determined whether products are "drugs".

Whether the Products are solely cosmetics or cosmetics *and* drugs is not "a complicated matter of first impression." As noted in the FDA's Cosmetic Policy Guide, courts can and do determine whether a cosmetic is a drug or both a cosmetic and a drug. U.S. Food and Drug Administration, Cosmetic Labeling Guide ("FDA Cosmetic Labeling Guide"), *available at* https://www.fda.gov/cosmetics/labeling/regulations/ucm126444.htm, at 4 (section titled "'Intended use' within the meaning of the FD&C Act is determined from its label or labeling") (Syverson Decl., Ex. B); Request For Judicial Notice, filed herewith; *see also Pantron I*, 33 F.3d at 1104-05 (affirming district court's finding that defendant's hair product is a "drug"); *Line Away*, 415 F.2d at 372 (same regarding lotion product); *Sudden Change*, 409 F.2d at 738-42 (finding lotion product making skin lifting representations was a drug); *Allergan II*, 738 F.3d at 1356 (affirming district court's order that the defendant objectively intended its RevitaLash products to be drugs).

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2. This Court, too, is fully capable of determining whether the Products are cosmetic drugs.

There is no need for this Court to defer to the FDA's expertise. The FDA has defined what constitutes a "drug" (Compl. ¶¶ 6, 24) and what constitutes a "cosmetic" (*id.* at ¶ 23), has given examples of both (*id.* at ¶¶ 8 (citing FDA's "Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)"), 27-30), and has given guidance in several warning letters to manufacturers (*id.* at ¶¶ 27-30), such that the Court is not shooting in the dark in determining whether the Products are cosmetic drugs. Defendant's efforts to downplay the significant guidance provided by the FDA by arguing that the warning letters are only "informal and advisory" in nature (Motion at 7, fn. 6), fail. It is precisely *because* the warning letters are advisory that Plaintiff cites them – they provide guidance to the Court.[7]

Defendant's argument that some of the warning letters cited in the Complaint include *cellular or tissue damage* repair claims (Motion at 18-19, fn. 14), fares no better. As Plaintiff alleges, by promising analogous material, lasting, and non-superficial skin structural effects, the Products are drugs, just like the products in the FDA warning letters. Compl. ¶¶ 27-30; *Pantron I*, 33 F.3d at 1105. Also failing is Defendant's argument that the warning letters indicate that the FDA has taken an active interest in policing the area such that the Court should step aside. Motion at 18-19. That argument is belied by the fact that, when the Southern District referred the *Nivea* cosmetic drug claims to the FDA, the FDA elected not to

[7] Interestingly, Defendant argues on one hand that the FDA's warning letters "have no legal significance" (Motion at 7, fn. 6), and argues on the other hand that the FDA's non-binding "Marketed Unapproved Drugs" guidance supports a stay of this litigation. *Id.* at 15-16, fn. 12. Defendant cannot have it both ways – either informal FDA guidance is helpful to this Court or it is not. And, although the guidance on "Marketed Unapproved Drugs" indicates the FDA may provide a "grace period" in certain circumstances, there is nothing prohibiting the Court from allowing for a similar "grace period" to the extent the Court found that to be appropriate here.

take action and instead allowed plaintiff's private action to proceed.[8] *Franz v. Beiersdorf, Inc.*, No. 14-cv-02241-LAB-RBB, Dkt. No. 37-1, FDA's response to plaintiff's Citizen Petition (Syverson Decl., Ex. A). As the FDA has limited resources, recently declined to resolve the issue, and has provided guidance on the issue, the Court should exercise jurisdiction so as not to delay this case and prejudice Plaintiff. *See* 21 C.F.R. § 10.30(e)(1) (in answering a Citizen Petition, the FDA is required to consider agency resources, priority of the petition, and time requirements); *see also Patane*, 2019 WL 1398052, at *4 ("Accordingly, I decline to dismiss or stay this case on primary jurisdiction grounds. Nestle has not shown adequate reason to believe that any kind of referral to the FDA would advance this litigation and do so without occasioning needless delay").

Further, whether a "cosmetic" is also a "drug" depends on its "intended use." Compl. ¶¶ 24 (citing 21 U.S.C. § 321(g)(1)(C)), 26 (citing Health & Safety Code §109925(c)). This is an objective test. "[I]ntent may be derived or inferred from labeling, promotional material, advertising, or any other relevant source." *U.S. v. Storage Spaces Designated Nos. 8 & 49 Located at 277 E. Douglas, Visalia, Cal.*, 777 F.2d 1363, 1366 (9th Cir. 1985); *U.S. v. Kasz Enterprises, Inc.*, 855 F. Supp. 534, 540 (D.R.I.) amended, 862 F. Supp. 717 (D.R.I. 1994) (same); *see also* 21 C.F.R. § 201.128 ("[O]bjective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives."); FDA Cosmetic Labeling Guide (Syverson Decl., Ex. B), at 4 ("'Intended use' within the meaning of the FD&C Act is determined from its label

[8] The FDA's no action decision in *Franz* was not an agency determination on the lawfulness of the defendant's labeling and did not undermine the plausibility of plaintiff's unlawful allegations. *See* 21 C.F.R. § 10.85(k) (FDA's response to Citizen Petition authorized by Deputy Director "does not communicate an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed."). Here, too, if the FDA declined to take action, it would not mean the Products are being lawfully sold.

or labeling.").

The FDA is in no better a position to decide the objective intended use of the Products than this Court. On this exact issue, determining whether mascara products were intended to be drugs, the court in *Allergan, Inc. v. Athena Cosmetics, Inc.*, 2012 WL 12895673, at *6 (C.D. Cal. May 16, 2012) ("*Allergan I*") stated:

> Any level of expertise required to make the present determination [whether or not defendant's products are drugs] is not the type that is beyond the Court or more likely found in an administrative agency. Nor is that expertise so great that the Court should defer to a possible agency determination. As the Court described above, the determination at issue is solely one of objective intent. There are no pharmacological or physical property determinations required.

Indeed, courts regularly make determinations regarding intent. *See, e.g., Allergan II*, 738 F.3d at 1356 (affirming district court's order that objective intended use of RevitaLash products indicated they were drugs). And Plaintiff has provided this Court with information to inform that decision. Compl. ¶¶ 18-21 (evidence that Products are intended to be drugs include: (1) Defendant features Pro-Retinol on the Product labels; (2) Defendant promises more immediate cosmetic effects, while the skin structural benefits require longer to take effect; (3) Defendant sells other skin care products that only make cosmetic claims; and (4) Defendant encourages consumers to use the whole line of Revitalift and Ultra-Lift products for "best results", indicating that the Products will provide a lasting, as opposed to a temporary effect). Indeed, the FDA has already indicated that featuring an ingredient like Retinol can indicate a product is a drug. *E.g.*, Compl. ¶ 8 (citing U.S. FOOD & DRUG ADMINISTRATION, Is It a Cosmetic, a Drug, or Both? (Or

Is It Soap?), *available at* https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm ("Intended use may be established in a number of ways" including where there are "[i]ngredients that cause a product to be considered a drug because they have a well-known (to the public and industry) therapeutic use)).[9]

Thus, unlike in *Franz*, 2015 WL 4659104, at *5 (S.D. Cal. Aug. 5, 2015) (Motion at 18), where plaintiff did not "provide any indication regarding how the FDA would view [defendant's representations]", *Figy v. Lifeway Foods, Inc.*, 2014 WL 1779251, at *5 (N.D. Cal. May 5, 2014) (Motion at 17-18), where the FDA was actively considering "the very issues that form the lynchpin of plaintiff's claims", and *Imagenetix, Inc. v. Frutarom USA, Inc.*, 2013 WL 6419674, at *5 (S.D. Cal. Dec. 9, 2013) (Motion at 17-19), where plaintiff did not provide the alleged "guidance on all of the relevant issues" to the court, the FDA has recently declined to resolve the issue and Plaintiff has provided the Court with persuasive "indication" that the repair and restore representations are "drug" claims.

3. Reclassification is not at issue.

Whether a product is properly ***classified*** as a drug and whether it is ***intended***

[9] Significantly, there are some forms of retinols that are deemed to be drugs. For example, in 2016 the FDA approved a form of retinol called Differin Gel 0.1% (adapalene) for the over-the-counter treatment of acne. U.S. Food & Drug Admin., FDA approves Differin Gel 0.1% for over-the-counter use to treat acne, FDA News Release (July 8, 2016), *available at* https://www.fda.gov/news-events/press-announcements/fda-approves-differin-gel-01-over-counter-use-treat-acne. This document is a published government record appearing on the FDA's website, the authenticity of which is not the subject of dispute, and the document is thus properly subject to judicial notice by this Court. *Gerritsen v. Warner Bros. Entm't Inc.*, 2015 WL 4069617, at *12 (C.D. Cal. Jan. 30, 2015) ("Under Rule 201, the court can take judicial notice of public records and government documents available from reliable sources on the Internet, such as websites run by governmental agencies.") (internal citations, quotation marks, and brackets omitted); *see also Daniels–Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998 (9th Cir. 2010) (it is "appropriate to take judicial notice" of information "made publicly available by government entities" on a website where neither party disputes the authenticity of the website nor the accuracy of the information displayed).

to be sold as a drug are two very different issues. Plaintiff seeks the latter determination only. Defendant's reliance on *Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645 (1973) (determination of whether a drug is generally recognized as safe and effective and thus not a "new drug" under FDCA) and other cases concerning "classification" of drugs is, therefore, misplaced. *See Allergan I*, 2012 WL 12895673, at *5, *6. And, *Estee Lauder, Inc. v. U.S. Food & Drug Admin.*, 727 F. Supp. 1 (D.D.C. 1989) (Motion at 17), is distinguishable because there, unlike here, the cosmetic manufacturer failed to exhaust its administrative remedies in challenging the FDA's informal opinion that its cosmetic was being sold as an unapproved drug.

4. Uniformity in administration is not implicated as the issue is highly contextual.

Finally, this case does not call for "uniformity in administration." Motion at 17-18. Considering this very question, the court in *Allergan I* stated:

> [T]he need for uniformity of administration is not strongly implicated. While many cosmetic products may use language similar to that used in Athena's current marketing, any decision by the Court would be highly dependent on the context surrounding the use of such language. *Estee Lauder*, 727 F.Supp. at 4 (discussing that a determination of intent is not dependent solely on the use of one or two words in product claims but also the context of that use, past labeling and advertising, and present labeling and advertising). A highly contextual determination for one set of products is unlikely to create uniformity in administration problems just from the fact a court makes a determination and an agency may make others. To the extent uniformity in administration is achievable, it will be uniformity in the high level concepts, not in the more specific fact based context

> determinations. Therefore, the Court finds this factor does not favor staying the case.

2012 WL 12895673l at *7.

This action, like *Allergan I*, does not seek to establish any particular standard. It only asks whether, based upon an objective evaluation of the representations on the labeling, Defendant represents that its Product affects skin structure. And, as discussed above, Plaintiff has provided the Court with clear guidance from the FDA (unlike in *Franz* and *Figy*). Thus, federal regulation in the area will not be disrupted or undermined by the enforcement of California's unfair competition law. *See Chavez v. Blue Sky Natural Beverage Co.*, 268 F.R.D. 365, 375 (N.D. Cal. 2010) ("Plaintiff's state law [false advertising] claims would not, however, threaten the integrity of the FDA's regulatory scheme governing misbranded food and do not implicate technical and policy questions that are reserved for the FDA . . . . [T]he FDA has traditionally regarded state law as an additional layer of consumer protection that complements FDA regulation.").

Defendant's argument that a "case-by-case approach is inherently unfair" (Motion at 18), is akin to arguing that, so long as everyone else violates the law, Defendant should be able to do so. *That* is what would be unfair because, as Plaintiff alleges, other manufacturers *are* complying with the law. Compl. ¶ 33 ("By making the unlawful representations Defendant is also able to charge a substantial premium for its Products over what it and its competitors charge for similar cosmetic products which, for example, claim only to moisturize and visibly improve the skin's appearance or look and do not make the unlawful drug claims.").

And, Defendant's reliance on *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010) (Motion at 19) and *Mollicone v. Univ. Handicraft, Inc.*, 2017 WL 440257 (C.D. Cal. Jan 30, 2017) (Motion at 20), is misplaced. The phrase "primary

jurisdiction" appears nowhere in *PhotoMedex*, and the opinion is limited to "the particular circumstances of [the] case, where the FDA permits Defendants to determine in the first instance whether their laser device was covered by clearance previously given to a similar device and to market their device without an affirmative statement of approval by the FDA" such that it was "impossible" for plaintiff to prove that defendants' competing medical device had allegedly not been cleared by the FDA. 601 F.3d at 922, 928. In *Mollicone*, the court based its primary jurisdiction holding on *Weinberger* and *Carnohan*, which concerned whether a drug is generally recognized as safe under FDA regulations and whether the drug Laetrile could be used in a nutritional program for the prevention of cancer, respectively, both of which are factually distinguishable from this case.

II. CONCLUSION

Because Plaintiff spent money on Products that should not have been on the market, she has Article III and UCL standing. Because Plaintiff's UCL claim is based on a violation of the Sherman Law, which is parallel to but *independent of* the FDCA, her claim is not preempted. And, because the issue of whether the Products are cosmetic "drugs" turns on an objective, intended use test that courts can and do determine, there is no reason to unnecessarily delay this case by referring it to the FDA under the doctrine of primary jurisdiction. Defendant's Motion should be denied in its entirety.

Dated: May 24, 2019

BONNETT, FAIRBOURN, FRIEDMAN & BALINT, P.C.

s/Patricia N. Syverson

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CERTIFICATE OF SERVICE

I hereby certify that on May 24, 2019, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the Electronic Mail notice list, and I hereby certify that I have mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the Manual Notice list.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed the 24th day of May 2019.

/s/ Patricia N. Syverson
Patricia N. Syverson